

POMPEJUS et al. Serial No. 09/582,779

Remarks

Claims 1 to 15 are pending in this application. Claims 1, 2 and 10 have been amended.

That the examiner has corrected several typographical errors in the specification is noted with appreciation.

The examiner is requested to favorably reconsider the objection to claim 10 in view of the foregoing amendment. The duplicative material has been removed as suggested by the examiner.

The examiner is requested to favorably reconsider the rejection of claims 1-4 under 35 U.S.C. 101 in view of the foregoing amendment to claim 1 which indicates that the gene has been isolated from its naturally occurring form. In addition to page 4, lines 24-29 of the applicants's specification to which the applicants previously referred, the examiner is directed to the examples in the specification, especially page 9, example 1, which clearly states that the claimed gene is isolated from *Ashbya gossypii* by common lab techniques described in numerous laboratory manuals. Favorable reconsideration is solicited.

The examiner is requested to favorably reconsider the rejection under 35 U.S.C. 112, second paragraph, as being indefinite in view of the foregoing amendment. The phrase "derive from" has been replaced by "isolated from" as suggested by the examiner.

Claims 1-15 stand rejected under 35 U.S.C. 112, first paragraph as relating to subject matter not adequately described in the specification. This rejection is traversed

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for the reasons advanced in the response filed on August 3, 2001. In addition, the applicants respectfully submit that the Federal Circuit in *Regents of University of California v. Eli Lilly & Co.*, 119 F.2d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997), provided guidance for an applicant wishing to claim a genus of DNA molecules:

A description of a genus of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus.

119 F. 3d at 1569, 43 USPQ2d at 1406

Although the Federal Circuit acknowledged that it may not be necessary to enumerate a plurality of species if a genus is sufficiently identified in an application by "other appropriate language," the court declined to speculate in what other ways a broad genus of genetic material may be properly described. *Id.*

In light of the above authority, the issue in the present case seems to be whether a "representative number of species (homologs) within the genus (SEQ ID NO:1) has been described. Despite the examiner's negative response to the applicants' arguments, it is firmly urged that since the sequence of SEQ ID NO:1 is disclosed, the sequence of homologs having at least 80% homology is also disclosed. There is only 20% variability. This especially seems to be true given the fact that, as a person skilled in the art knows, a particular sequence easily can be modified by genetic engineering to yield homologs which do not affect the activity of the corresponding protein.

In view of the foregoing amendment and remarks, the applicants respectfully urge that the invention claimed herein is patentable and a Notice of Allowance is

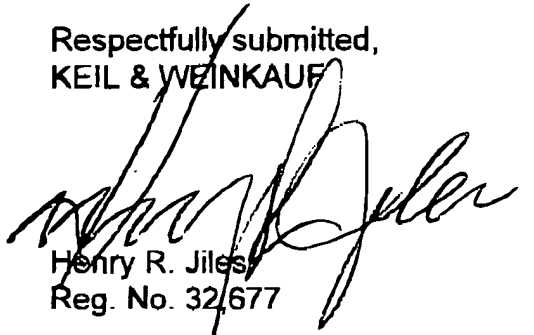
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solicited.

**Please find attached a check for \$110.00 for a one month extension of time fee.**

To the extent necessary, applicant(s) petition for an Extension of Time under 37 CFR 1.136. Please charge any shortage in fees due in connection with the filing of this paper, including Extension of Time fees to Deposit Account No. 11-0345. Please credit any excess fees to such deposit account.

Respectfully submitted,  
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**VERSION WITH MARKINGS TO SHOW CHANGES MADE IN THE CLAIMS**

Please claims 1, 2 and 10 have been amended to read as follows:

1. (amended) An orotidine-5'-phosphate decarboxylase gene having the sequence  
SEQ ID NO: 1 or its homologs isolated from microorganisms which have at least  
80% homology with the sequence SEQ ID NO: 1.
  
2. (amended) An orotidine-5'-phosphate decarboxylase gene having the sequence  
SEQ ID NO: 1 or its homologs [derive] are isolated from *Ashbya gossypii*.
  
10. (twice amended) A process for inserting DNA into microorganisms, which  
comprises inserting a vector which comprises an intact orotidine-5'-phosphate  
decarboxylase gene having the sequence SEQ ID NO: 1 or its homologs isolated  
from microorganisms which have at least 80% homology with the sequence SEQ  
ID NO: 1 as claimed in claim 1 together with at least one other nucleic acid  
sequence, into a microorganism [ which is deficient in orotidine-5'-phosphate  
decarboxylase nucleic acid sequence having the sequence SEQ ID NO: 1 or its  
homologs as claimed in claim 1 together with at least one other nucleic acid  
sequence, into a microorganism ] which is deficient in orotidine-5'-phosphate  
decarboxylase nucleic acid sequences, and cultivating this microorganism on or  
in a culture medium without uracil.